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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,177	11/23/2001	George A. Cates	1038-1168 MIS:jb	6952

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/868,177	CATES ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-14,20 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3, 5-14, 20 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Currently, claims 3, 5-14, 20 and 21 are pending in the application. The claims were rejected in the Final action, mailed on December 17, 2003. In the After-Final Response, filed on June 16, 2004, the Applicant amended claims 3,5, 6, 8-11, 14, and 20; and canceled claims 4 and 15-18.

2. In view of the new rejection raised in this action, the Finality of the prior action is withdrawn.

Specification

3. **(Prior Objection-Withdrawn)** The use of the trademark Fluzone® has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. In view of the amendment of the specification to insert a generic descriptor for the indicated composition, the objection is withdrawn.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. **(New Rejection)** Claims 3, 5-14, 20, and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed immunogenic

compositions, does not reasonably provide enablement for such compositions that are effective for the protection of the host against disease caused by RSV. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In making a determination as to whether an application has met the requirements for enablement under 35 U.S.C. 112 ¶ 1, the courts have put forth a series of factors. See, In re Wands, 8 USPQ2d 1400, at 1404 (CAFC 1988); and Ex Parte Forman, 230 U.S.P.Q. 546 (BPAI 1986). The factors that may be considered include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. Id. While it is not essential that every factor be examined in detail, those factors deemed most relevant should be considered.

The rejected claims read on compositions or methods for conferring protection, or immunizing a human against, infection by RSV. The specification demonstrates in Examples 4-7 that the claimed compositions were effective at inducing the production of anti-RSV antibodies in mice. Thus, the Applicant has demonstrated that the claimed compositions are effective immunogenic compositions.

However, the specification does not demonstrate that the claimed compositions protect the host against infection by RSV, or that such compositions would be effective in humans. Further, the art teaches that, although numerous vaccine candidates have been tested, several challenges have arisen in the development of such vaccines which have prevented the

identification of one that is safe and effective in people. See e.g., Prince et al., J Virol 74: 10287-92 (teaching difficulties faced in the multiple types of RSV vaccines attempted in the art on page 10287); and Tang et a1., J Virol 7420: 10819-28 (teaching on page 10819 that both potential subunit or inactivated RSV vaccines have failed due to immunogenicity or safety reasons during the past few decades). Additionally, the art also indicates that, while the use of accepted models for a disease may sometimes be predictive of human responses to a potential therapy, such is not presently the case with RSV infections. In particular, the art does not show an acceptance of any particular animal model as predictive of human responses to RSV vaccines. See e.g., Dudas et al., Clin Microbiol Rev 11 (3): 430-39, esp. page 432 (indicating that although animal models provide information regarding the potential vaccines, the vaccines so identified have not been established as protective in humans). In view of these difficulties and uncertainties identified in the art, while the Applicant has demonstrated that certain embodiments of the claimed composition may be immunogenic, the Applicant has not enabled the use of the claimed attenuated virus as a vaccine for humans.

Claim Rejections - 35 USC § 103

6. **(Prior Rejection- Withdrawn)** Claims 1, 2, 5-18, and 20 were rejected in the prior action under 35 U.S.C. 103(a) as being obvious over Cates et al. U.S. Patent 6,020,182 (Cates U.S.), in view of Smith et al., U.S. Patent 5,762,939, and Webster et al., U.S. Patent 5,824,536. Claims 1, 2, and 15-18 have been cancelled from the application. The remaining claims have been amended to read on immunogenic compositions, or methods of using compositions, comprising fusion (F), attachment (G), and matrix (M) proteins of respiratory syncytial virus

(RSV), and a combination of the adjuvant PCPP and the anti-influenza vaccine Fluzone®. As was indicated in the prior action, the Applicant has established unexpected results with respect to this combination. Because the pending claims have been amended to read on this combination of elements, the rejection is withdrawn.

7. **(Prior Rejection- Withdrawn)** Claims 1, 2, 5-18, and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cates et al., WO 98/02457 (Cates PCT), published Jan. 22, 1998, in view of Smith et al., U.S. Patent 5,762,939, and Webster et al., U.S. Patent 5,824,536. The amended claims have been described above, In view of the claim cancellations and amendments described above, this obviousness rejection is withdrawn.

8. **(Prior Rejection- Withdrawn)** Claims 1, 2, 4, 6-14, and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S. or Cates PCT as applied to claims 1, 2, 5-18, and 20 above, and further in view of Payne, Vaccine, Vol. 16(1): 92-98. The amended claims have been described above, In view of the claim cancellations and amendments described above, this obviousness rejection is withdrawn.

(Prior Rejection- Withdrawn) Claim 4 was rejected in the prior action under 35 U.S.C. 103(a) as being unpatentable over Cates PCT in view of Andrianov, U.S. 5,494,673. This claim has been cancelled from the application. The rejection is therefore withdrawn.

9. **(Prior Rejection- Withdrawn)** Claims 1, 2 5-16, and 20 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., or Cates PCT, as applied to claims 1, 3, and 6-18 above, and further in view of Huebner, U.S. Patent 5,612,037. The amended claims have

been described above, In view of the claim cancellations and amendments described above, this obviousness rejection is withdrawn.

10. **(Prior Rejection- Withdrawn** Claims 20 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., in view of Smith and Webster or in view of Huebner as applied above to claims 1, 3, and 6-18, and further in view Murry et al., Hosp. Pract. 32(7): 87-8, 91-4. The amended claims have been described above, In view of the claim amendments described above, this obviousness rejection is withdrawn.

11. **(Prior Rejection- Withdrawn)** Claims 20 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., or Cates PCT, in view of Smith and Webster, or in view of Huebner as applied to claims 1, 3, 6-15, and 18 above, and further in view of Potash, U.S. 5,911,998. The amended claims have been described above, In view of the claim amendments described above, this obviousness rejection is withdrawn.

12. **(Prior Rejection-Withdrawn)** Claims 20 and 21 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cates U.S., in view of Smith and Webster or in view of Huebner as applied above to claims 1, 3, and 6-18, and further in view of Hall et al., J. Infect. Dis., 163:693-698; Crowe, Vaccine, 13:415-421; Groothuis, Journal of Infectious Diseases, 177(2), pp. 467-469 (1998); and Falsey, Vaccine, 14(13), pp. 1214-1218 (1996). The amended claims have been described above, In view of the claim amendments described above, this obviousness rejection is withdrawn.

13. **(Prior Rejection- Withdrawn)** Claims 1, 2, 4, 6-21 were rejected under 35 U.S.C. 103(a) as being obvious over claims 1-9, 13, 15-21, 23, and 26 of copending Application No. 09/950655 (discussed in reference to the Pre-Grant Publication of this application as PG Pub

2002/0136739), in view of Smith, Webster, Payne, and Murry. The amended claims have been described above, In view of the claim amendments described above, this obviousness rejection is withdrawn.

Double Patenting

14. **(Prior Rejection- Withdrawn)** Claims 1-10, 12-16, 20, and 21 were provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3-11, 13-18, and 20 of copending Application No. 09/213, 770. In view of the amendment of the claims to include the limitations of claim 3, the rejection is withdrawn.

15. **(Prior Rejections-Withdrawn)** Claims 1, 2, 4-16, 18, 19, 20, and 21 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, and 13 of U.S. Patent No. 6,020,182, in view of Smith et al., U.S. Patent 5,762,939 and Payne. Claims 1, and 2, 5-21 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 6-16 of U.S. Patent No. 6,309,649, in view of Smith et al., U.S. Patent 5,762,939 or Palese et al., U.S. Patent 6022726. Claims 1, 11, 15, and 17-19 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-11, 13-18, and 20 of copending Application No. 09/213, 770, or over these claims in view of Smith or Palese. Claims 1, 2, 4, 6-21 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9, 13, 15-21, 23, and 26 of copending Application No. 09/950655 (discussed in reference to the Pre-Grant Publication of this application as PG Pub 2002/0136739), in view of Smith, Webster, Payne, and Murry. In

view of the amendment of the claims as described above (requiring the limitations of the claim 3 describing the combination of the RSV and Fluzone® compositions and PCPP), these rejections of the claims are withdrawn.

Conclusion

16. No claims are allowed.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner

JAMES HOUSEL 7/12/04
SUPERVISORY PATENT EXAMINER
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